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09/830,807	07/16/2001	Helen Rachel Crooke	GJE-65	2112

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,807

Applicant(s)

CROOKE ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. The amendment filed on December 19, 2003 has been entered. Claims 1-8 and 10-22 have been cancelled. Claim 9 has been amended. Claims 23-40 are newly added. Claims 9 and 23-40 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments:

- a) the written description, enablement and new matter rejections of claims 18-19 under 35 U.S.C. 112, first paragraph; and
- b) the rejection of claims 18-19 under 35 U.S.C. 112, second paragraph

Response to Arguments

3. Applicant's arguments filed December 19, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained. The rejection was on the grounds that claim 9 fails to recite any method steps. Applicants' assert that a reasonable degree of latitude should be applied

Art Unit: 1645

when the examiner is asserting that the rejected claim lacks method steps and that the amount of method steps recited by the claim is at applicants' discretion.

However, the examiner is not dictating the literal terms of the claims as applicants' suggest. Rather, the examiner is stating that the claims fail to recite any steps associated with a method for screening potential drugs. There are no steps recited. There is not even a step that requires the potential drug to be introduced or contacted with the peptide. There are no steps relating what type of screening is being performed. There are no steps that detect any changes, such as a change in growth, biological activity, presence or absence of expression, binding between proteins or the translocation of some protein from the bacterial cytoplasm to the periplasm. Merely reciting that the method step utilizes a peptide without reciting any steps to achieve a method for screening for potential drugs is insufficient. Moreover, the specification fails to teach any steps for the claimed method since the specification is silent with respect to methods for screening potential drugs. Thus, neither the claims nor the specification teach method steps necessary to accomplish a method for screening for potential drugs and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1645

5. Claim 9 and 23-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims drawn are to a method of screening using a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level. However, the written description in this case fails to sets forth a method of screening using a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level.

The instant specification fails to provide an actual method for screening potential drugs. There is no description of any peptide with ability to translocate proteins and

Art Unit: 1645

there is no teaching of what protein is being translocated. There is no description of homologues or functional fragments of any of the *tatA*, *tatB*, *tatC*, *tatE*, genes or SEQ ID NO: 11, 12, 13, and 15 wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level. There is no teaching of a screening method using the claimed peptides. There is no disclosure of actual homologues or functional fragments that could be used in the undisclosed method of screening and there are not even any representative examples of such homologues or functional fragments which meet the percent homology limitations. There is no written description of any method for screening potential drug steps. There are no examples that teach the claimed peptides, homologues or functional fragments with ability to translocate proteins that can be used within the method. There is no teaching of an actual screening of any potential drug. It is unclear that one of skill in the art could create peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level for use in the screening method based on the instant specification.

Applicants' assertion that merely stating that genes and peptides can be used as targets for screening potential drugs reasonably conveys to one of ordinary skill in the art that the inventors were in possession of the claimed invention is not sufficient. As previously stated the instant specification fails to provide a protocol that teaches method

Art Unit: 1645

steps for screening potential drugs. Applicants' have failed to even incorporate by reference a screening method as instantly claimed. Applicants have no representative examples of peptides that meet the limitation of being a homologue or functional fragment obtainable from a Gram-negative bacterium that has at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level to any of *tatA*, *tatB*, *tatC*, *tatE*, genes or SEQ ID NO: 11, 12, 13, and 15. Finally the specification recitation that "According to another aspect of the invention, the peptides or genes may be used for screening potential antimicrobial drugs or for the detection of virulence" at page 2 lines 15-17 is not sufficient to meet the written description requirements.

Sequences having at least 30%, 70%, 80% or 90% homology to any of SEQ ID NO:11, 12, 13, or 15 fail to meet the written description provision of 35 UCS 112, first paragraph. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The specification only discloses SEQ ID NO:11, 12, 13 and 15, there is no disclosure of amino acid or nucleotide sequences with at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level that encode peptides that can be used within the method for screening potential drugs. Thus, the structure of these amino acid and nucleic acid

Art Unit: 1645

molecules are not defined. Even though claims 28-34 and 37-40 recite sequence identification numbers, the skilled artisan cannot envision the detailed structure of the sequences having at least 30%, 70%, 80% or 90% homology to the nucleotide or amino acid since the specification has failed to define what the regions of the peptide are essential in the peptides performance within the screening method. Clearly, there is at least one essential region that allows the peptide to have the ability to translocate a protein from the bacterial cytoplasm to the periplasm, yet the specification fails to teach such region. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The specification does not provide any peptides, homologues or functional fragments comprising an amino acid sequence having at least 30% homology to SEQ ID NO: 11, 12, 13 and 15 or any polynucleotide structures that encode peptide useable in the screening method. There is no teaching of which amino acids or nucleic acids may or may not be changed without causing detrimental effects towards the method of screening. Applicants have not shown that by modifying a reference sequence encoding a reference polypeptide, will automatically predict the peptide useable in the screening method as instantly claimed. The specification fails to teach the structure or relevant identifying characteristics of a representative number of peptides, homologues

Art Unit: 1645

or functional fragments sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Thus a skilled artisan cannot envision all the contemplated amino acid and nucleotide sequences by the detailed chemical structure of the claimed peptides and therefore conception cannot be achieved until reduction to practice has occurred. Furthermore, *In The Regents of the University of California v. Eli Lilly*, (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids does not provide an adequate written description of the genus. Applicants are not required to disclose every species encompassed by a genus, thus the description of a genus is achieved by the recitation of a representative number of SEQ ID NO's, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a nucleic acid molecule...requires a precise definition, such as by structure, formula, chemical name, or physical properties".

The claims fail to recite the precise definition of the peptides, homologues and functional fragments. Currently the generic recitation is insufficient to support the claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Applicants' arguments about how to obtain sequence homology do not cure the issue that applicants have failed to provide even one representative example of a homologue or functional fragment obtainable from a Gram-negative bacterium that has

Art Unit: 1645

at least 30%, 70%, 80% or 90% homology at the nucleotide or amino acid level to any of *tatA*, *tatB*, *tatC*, *tatE*, genes or SEQ ID NO: 11, 12, 13, and 15. Applicants also assert that the Lee and Ochsner et al., state that it is well conserved among important bacterial pathogens, however it is noted that the instant specification fails to incorporate either reference. Moreover, the instant specification fails^{to} disclose functional fragments and the fact that an unincorporated reference discloses functional fragments does not provide adequate written description to the instant specification. The written description requirements are drawn to the teachings of the instant specification, and the instant specification fails to protein translocation ability, truncation of peptides, retaining specific functional regions or a screening method. Therefore, the instant specification fails to meet the written description requirements.

Contrary to applicants' assertion that because SEQ ID NO:11, 12, 13 and 15 fulfill the written description requirements, thus sequences having at least 30% homology also meet said requirements is incorrect for the reasons stated above. The specification fails to teach the structure or relevant identifying characteristics of a representative number of polynucleotides encoding a representative number of polypeptides sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Therefore one skilled in the art could not envision all the contemplated amino acid and nucleotide sequences by the detailed chemical structure and therefore conception cannot be achieved until reduction to practice has occurred. Therefore, the full breadth of the claims fails to meets the written description provision of 35 USC 112, first paragraph.

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of a method for screening potential drugs as instantly claimed.

6. Claims 9 and 23-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amended and new claims are drawn to a method for screening a potential drug using a peptide wherein claims 23-40 comprise a contact step and a determination step. However there is no support within the entire application for a method of screening using a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level. First there is no passage within the specification recites using such peptides in a method for screening. Applicants point to pages 2,5 and 16 of the instant specification for support, however those pages merely state that the peptides or genes may be used for screening potential antimicrobial drugs. There is no

Art Unit: 1645

recitation of a peptide that has the ability to translocate a protein from the bacterial cytoplasm to the periplasm or a peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, and *tatE* or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level that is used in a method for screening potential drugs. There is no support by way of examples of a homologue or functional fragment of any of the *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO:11, 12, 13, and 15 wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level. Applicant failed to point to support in the specification for the recited method that utilizes the claimed peptide. Therefore, applicants must specifically point to page and line number support for the newly added amendments drawn to a method of screening using a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level or cancel the claims. Therefore, the claims incorporate new matter and are accordingly rejected.

7. Claims 9 and 23-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not appear to teach a method for screening a potential drug using a peptide wherein claims 23-40 comprise a contact step and a determination step. There is no teaching within the entire application of a method for screening potential drugs using a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level.

Furthermore, the specification fails to state what steps are comprised within the method to achieve screening for potential drugs. The specification fails to teach examples of screening for potential drugs using the claimed operon. The specification simply states that peptides can be used in screening methods. The prophetic language of the specification fails to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Applicants have provided no guidance to enable one of skill in the art how to use, without undue experimentation, the method for screening potential drugs utilizing a peptide encoded by an operon without appropriate positively recited steps. Moreover, there are no examples of said method using the claimed operon. There are no examples of homologues or functional fragments, and there are no examples of using homologous or functional fragments in a method of screening potential drugs. Thus, simply mentioning that peptides may be used in a screening method does not enable a method that has no recited steps. Moreover, it does not enable a method claiming the use of peptides that are not adequately described. Given the lack of guidance contained in the specification and the unpredictability for a method that screens for potential drugs using peptide or homologue or functional fragment, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Furthermore, the specification fails to provide an enabling disclosure for the utilization of the claimed operon that meets the limitations recited in the claims. Applicants' have provided no guidance to enable one of ordinary skill in the art as to how determine, without undue experimentation, a method for screening potential drugs wherein the method uses a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30%

homology at the nucleotide or amino acid level. Moreover, applicants never even performed the method to determine whether the method is actually useful in screening potential drugs. Thus a skilled artisan would have to de novo determine the steps required to perform said methods. Given the lack of guidance contained in the specification and the unpredictability for the methods, one skilled in the art could not make or use the broadly claimed invention without undue experimentation.

The claims recite at least 30% homologous to any amino acid or nucleotide level wherein the modification can be obtained by deletion, substitution or insertion of one or more amino acids or nucleotides, however the specification provides no guidance as to what amino acids or nucleotides may or may not be changed without causing a detrimental effect to the peptide to be produced. The claims broadly teach 30% homology which includes substitution or insertion, and no specific location for where the deletion, substitution or insertion or any combination thereof is recited. If 70% of the nucleotides/amino acids are substituted or inserted the resulting peptide will result in a polypeptide not taught and enabled for its use in a method for screening potential drugs as instantly claimed. Moreover, the scope of the claim is unduly large and it is clear that the skilled artisan will find hundreds of proteins with as little of 30% homology, most of which will be completely unrelated to the listed proteins. The claims thereby include virtually every protein, any variation thereof, and any fragment despite the fact that said claims are not enabled.

Neither the claims nor the specification teach how to obtain a 30% homologous peptide by deletion, substitution or insertion of one or more amino acids. There is no guidance as to what nucleotides may or may not be changed without causing a detrimental effect to the polypeptide being claimed, and no specific location for where

the deletion, substitution or insertion or any combination is recited. Thus, the resulting polypeptide could result in a polypeptide not taught and enabled by the specification. The discussed in the previous office action, the prior art teaches that variation of the primary structure of a protein can result in an instable molecule; and it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect. No working examples are shown containing the missing information about a method for screening potential drugs using a peptide, encoded by an operon wherein the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and wherein the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level. There are no examples of an enabled method of screening. Without such information, one of skill in the art could not predict which deletions, substitutions or insertions or any combination thereof would result in the desired stable peptide that could be used in method for screening potential drugs wherein the peptide is encoded by an operon and the peptide has the ability to translocate a protein from the bacterial cytoplasm to the periplasm and the peptide is obtainable from *E. coli* K1 and is encoded by an operon comprising a gene selected from the group consisting of *tatA*, *tatB*, *tatC*, *tatE*, SEQ ID NO: 11, 12, 13, and 15 or a homologue or functional fragment of any of the foregoing wherein the homologue is obtainable from a Gram-negative bacterium and has at least 30% homology at the nucleotide or amino acid level. Accordingly, one of skill in the art would be required to perform undue experimentation to de novo discover the appropriate steps and peptides useable within the screening method. Therefore, one

skilled in the art could not make and/or use the invention without undue experimentation.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 09/830,807
Art Unit: 1645

Page 17

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Ja-Na Hines 
March 11, 2004


LYNETTE R. F. SMITH
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